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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			LEAVITT, MARIA GOMEZ	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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OCT 28 2010

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C
ONE FINANCIAL CENTER
BOSTON MA 02111

In re Application of:
Peled et al.
Serial No.: 10/774,843 : PETITION DECISION
Filed: February 9, 2004
Attorney Docket No.: **24024-505 CON** :

This is in response to the petition filed December September 7, 2010 under 37 CFR § 1.181, requesting reconsideration of the Advisory Action of August 17, 2010 wherein it was set forth the that claim amendments and Declaration would not be entered.

BACKGROUND

The examiner mailed a non-final Office action on September 21, 2009 setting a three month statutory limit for reply in response to an RCE. Claims 401, 411, 414, 416, 419, 422-424, 437, 438, 464, 465, 469-471 and 478-480 were pending and were rejected. Claims 401, 411, 414, 416, 419, 422-424, 437, 438, 464, 465, 469-471 and 478-480 remained rejected under 35 USC 103 (a) as being unpatentable over Brown over Block et al. Claims 437 and 438 remained rejected under 35 USC 103 (a) as being unpatentable over Brown over Block et al. as applied to claims 401, 411, 414, 416, 419, 422-424, 437, 438, 464, 465, 469-471 and 478-480 above, and further in view of Banasik et al. Claims 411, 465 and 478-480 were newly rejected under 35 USC 101 because the claimed invention if drawn to non-statutory subject matter. Claims 401, 414, 416, 419, 422-424, 437, 438, 464, 465, 469-471 were newly rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

On January 21, 2010, applicants submitted amendments and remarks addressing the rejections set forth in the Office action of September 21, 2009.

On February 22, 2010, applicants submitted supplemental amendment and a Declaration under 37 CFR 1.132.

On April 30, 2010, the examiner mailed a final Office action setting a three month statutory limit for reply. In this action, Claims 401, 411, 414, 416, 419, 422-424, 464, 465, 469-471 and 478-480 were pending and were rejected. Claims 401, 411, 414, 416, 419, 422-424, 464, 465, 469-

471 and 478-480 remain rejected under 35 USC 103 (a) as being unpatentable over Brown over Block et al.

On July 30, 201, applicants submitted an amendment after final and a Declaration under 37 CFR 1.132.

On August 17, 2010, the examiner mailed an Advisory Action denying entry of the amendment after final and the Declaration under 37 CFR 1.132.

In response thereto, applicants filed a petition on September 7, 2010 under 37 CFR § 1.181, requesting reconsideration of the Advisory Action of August 17, 2010 wherein it was set forth the that amendments and Declaration would not be entered.

DISCUSSION

The petition and the file history have been carefully considered.

In the petition filed on September 7, 2010, applicants argue “The decision not to enter and consider the claim amendments proposed in the Response is based on the Examiner's assertion that the additional limitations in the independent claims were not previously examined and required a new search (*See*, Advisory Action at point 3 on page 2 and cont. of point 3 on page 3). Applicants submit that this assertion is incorrect. Rather, Applicants submit that the subject matter of the amendments made in independent claims 401 and 411 encompass the subject matter of dependent claims 464 and 465; and as such, these amendments were previously examined by the Office and do not require a new search (*See*, Response at pages 2-4).”

Applicants also argue “The decision not to enter and consider the Declaration of Dr. Tony Peled under 37 C.F.R. § 1.132 filed with the Response is based on the Examiner's assertion that the after-final Declaration is not directed to a new rejection first made in the Final Office Action but rather to the 35 U.S.C. § 103 rejection previously of record. (*See*, Advisory Action at point 11 on page 2 and cont. of point 11 on page 3). Applicants submit that this assertion is incorrect. Rather, 37 C.F.R. § 1.116(e) provides that an affidavit or other evidence submitted after a final rejection may be admitted upon a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not presented earlier. Applicants submit that such good and sufficient reasons are present here. Specifically, Applicants submit that the July 2010 Declaration of Dr. Peled was specifically directed to the Examiner's dismissal of a February 2010 Declaration of Dr. Peled and the Examiner's assertion, for the first time, in the Final Office Action that the evidence presented in that February 2010 Declaration was not statistically significant (*See*, Final Office Action at page 8). That is, the data/evidence provided in the July 2010 Declaration was not generally directed to the 35 U.S.C. § 103 rejection previously of record as asserted by the Examiner; but rather, evidence submitted to directly rebut the Examiner's statements first made in the Final Office Action (*See*, Response at page 7). As such, Applicants respectfully submit that the July 2010 could not have been presented earlier and is necessary to support the evidence provided in the February 2010 Declaration.”

Applicants' arguments have been carefully considered but they are not persuasive. The refusal to enter the amendment after final was an appropriate action taken by the examiner. Specifically, the limitation of 'up to three weeks' is still recited in claims 464 and 465, and to reject the limitation of the claims only requires adding nicotinamide for less than three weeks. Also, 'up to' may or may not include the three week time point. The current amendment requires culturing three weeks or 'after a three week culture period' (claim 411) (beyond three weeks not 'up to' anymore), and claim 401 requires 'three weeks' which is only one part of the scope that needed to be searched. Thus, the amendment introduces new issues, one being a new search since it is a new range requirement. As regards the Declaration, when comparing the two declarations, the data presented is not the simple addition of error bars to show significance in the results. There is a different experimental design to show trends over a period of time, and arguments are presented that are more consistent with the new amendment to the claims about more prolonged exposure times.

Accordingly, in view of the evidence, it is not seen that the action taken in the Advisory Action of September 7, 2010 is in error.

DECISION

The petition is **DENIED**.

Any new or renewed petition must be filed within TWO MONTHS of the mail date of this decision.

Should there be any questions about this decision please contact Marianne C. Seidel, by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0584 or by facsimile sent to the general Office facsimile number, 571-273-8300.



Jackie Stone
Director, Technology Center 1600